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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,011

10/07/2005

Harold Armando Gomez Torres

1556-0107PUS1

6281

2292 7590 03/20/2009
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EXAMINER

POCHAS, CHRISTOPHER M

ART UNIT

PAPER NUMBER

4121

NOTIFICATION DATE

DELIVERY MODE

03/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/552,011	Applicant(s) GOMEZ TORRES, HAROLD ARMANDO	
	Examiner Christopher Pochas	Art Unit 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/07/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

1) Applicant's election with traverse of Group I, claims 1-11 and 14-20 in the reply filed on 1/12/2009 is acknowledged. The traversal is on the ground(s) that if the composition is novel, the methods of its use must necessarily be novel. This is not found persuasive because gels containing papain as well as emulsifiers and preservatives are well known in the art.

The requirement is still deemed proper and is therefore made FINAL.

2) Claims 12 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/12/2009.

3) This application is a 371 of PCT IB2003/001295.

Non Final Rejection

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6190691.

Claims 1-3 U.S. Patent 6190691 (hereafter the 691 patent) discloses the use of a topical gel for treating, among various other things, burns. The composition of the invention of the 691 patent includes multiple gelling agents, papain, preservatives, anesthetics, antimicrobial agents, analgesics, and emulsifiers. These are taught in the section of 691 entitled "topical formulations" except for papain which is disclosed in the section entitled "iontophoresis". Topical gels are used in iontophoresis. The paragraph of line 37 of column 10 discloses that sunburn, a type of burn can be treated with the composition of its invention. The paragraph of line 5 of column 44 discloses that multiple thickeners may be used in the topical formulations of its inventions. The same paragraph discloses that these are also gelling agents (i.e. gels of pending claim 1). The paragraph of line 20 of column 44 of the 691 document discloses that the ingredients of the topical composition are mixed together, therefore one gelling agent would contain a emulsifier whereas the other would contain a preservative and vice versa. Proteolytic cleavage is disclosed in the paragraph of line 56 of column 69.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691.

Claims 1-3, 7, 8, and 14. The 691 patent discloses the use of a topical gel for treating, among various other things, burns. The composition of the invention of the 691 patent includes multiple gelling agents, papain, preservatives, anesthetics, antimicrobial agents, analgesics, and emulsifiers. Note that analgesics are a type of anesthetics as per pending claim 14. These are taught in the section of 691 entitled "topical formulations" except for papain which is disclosed in the section entitled "iontophoresis". Topical gels are used in iontophoresis. . The paragraph of line 37 of column 10 discloses that sunburn, a type of burn can be treated with the composition of its invention. The paragraph of line 5 of column 44 discloses that multiple thickeners may be used in the topical formulations of its inventions. The same paragraph discloses that these are also gelling agents (i.e. gels of pending claim 1). The paragraph of line 20 of column 44 of the 691 document discloses that the ingredients of the topical composition are mixed together, therefore one gelling agent would contain a emulsifier whereas the other would contain a preservative and vice versa. Concerning the specific ranges of pending claims 7 and 8, it is not inventive to discover the optimum or workable ranges by routine experimentation when all the conditions of a claim are present in the prior art. Proteolytic cleavage is disclosed in the paragraph of line 56 of column 69.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 5446070.

The 691 patent does not teach the specific ingredients of the pending claims besides papain.

U.S. Patent 5446070 (hereafter the 070 patent) discloses the use of lidocaine as a topical anesthetic.

It is not inventive to discover the optimum or workable ranges by routine experimentation when all the conditions of a claim are present in the prior art.

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to combine the teachings of the 070 patent and the 691 patent because the 070 patent teaches a specific topical anesthetic and the 691 patent teaches the use of anesthetics generally in its composition. Furthermore section 2144.06 of the MPEP states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art."

Claims 5 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 5051263.

The 691 patent does not teach the specific ingredients of the pending claims besides papain.

In paragraph 11 of the brief summary, U.S. Patent 5051263 (hereafter the 263 patent) discloses carboxypolymethylene as a gelling agent and thickener.

It is not inventive to discover the optimum or workable ranges by routine experimentation when all the conditions of a claim are present in the prior art.

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to combine the teachings of the 263 patent and the 691 patent because the 263 patent teaches a specific topical thickening agent and the 691 patent teaches the use of thickening agents generally in its composition. Furthermore section 2144.06 of the MPEP states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art."

Claims 6 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 5024838.

The 691 patent does not teach the specific ingredients of the pending claims besides papain.

U.S. Patent 5024838 (hereafter the 838 patent) discloses a topical composition containing papain and a vehicle in example 1 and carboxymethylcellulose is disclosed as the vehicle in the brief summary.

It is not inventive to discover the optimum or workable ranges by routine experimentation when all the conditions of a claim are present in the prior art.

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to combine the teachings of the 838 patent and the 691 patent because the 838 patent discloses that carboxymethylcellulose is a suitable vehicle for papain compositions such as that of the 691 patent.

Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 4276430.

The 691 patent does not teach the specific ingredients of the pending claims besides papain.

U.S. Patent 4276430 (hereafter 430) discloses in the paragraph of line 6 of column 12, a topical composition for the treatment of burns containing triethanolamine as an emulsifier.

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to combine the teachings of the 430 patent and the 691 patent because the 430 patent teaches a specific topical emulsifier and the 691 patent teaches the use of emulsifiers generally in its composition. Furthermore section 2144.06 of the

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MPEP states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art."

Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 544076.

The 691 patent does not teach the specific ingredients of the pending claims besides papain.

Line 52 of column 2 of U.S. Patent 544076 (hereafter the 076 patent) discloses methyl parabene and propyl parabene as preservatives in a topical composition.

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to combine the teachings of the 076 patent and the 691 patent because the 076 patent teaches a specific topical preservatives and the 691 patent teaches the use of preservatives generally in its composition. Furthermore section 2144.06 of the MPEP states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art."

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Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. patent 6121254.

The 691 patent does not teach the specific ingredients of the pending claims besides papain.

The paragraph of line 55 of column 2 of U.S. patent 6121254 (hereafter the 254 patent) discloses the use of chlorhexidine as an antibacterial agent in a topical composition.

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to combine the teachings of the 254 patent and the 691 patent because the 254 patent teaches a specific topical antibacterials and the 691 patent teaches the use of antibacterials generally in its composition. Furthermore section 2144.06 of the MPEP states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pochas whose telephone number is (571)270-7722. The examiner can normally be reached on Monday to Friday 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMP/

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121